BREXIT AND PHARMA

THE BAH CAMPAIGNS FOR STRONG ECONOMIC AND REGULATORY TIES

The decision of the United Kingdom to leave the European Union (EU) – so-called Brexit – will have far-reaching economic and regulatory consequences for the European economy and especially for German pharmaceutical manufacturers. The ultimate objective should be to maintain access to the British market – and this is what we at the German Medicines Manufacturers' Assocation (BAH) are campaigning for.

As the result of the decision of UK citizens on 23 June 2016 in favour of Brexit, the EU will lose its second largest national economy within Europe behind Germany. Pursuant to European law, the negotiations setting out the arrangements for the withdrawal must be completed by 30 March 2019. All parties expect the negotiations to take far longer; some even believe they could take up to ten years.

ECONOMIC AND REGULATORY CONSEQUENCES FOR PHARMA

Withdrawal of the United Kingdom from the European common market would have wide-ranging negative economic consequences for pharmaceutical manufacturers – from shipping trade delays in the simplest case to export losses in the extreme case. In 2015, German pharmaceutical manufacturers exported pharmaceuticals worth more than EUR 7 billion to the UK. Pharmaceutical goods worth about EUR 1.5 billion went in the opposite direction. German manufacturers would especially feel the effects of a loss of the British market.

Brexit would also have an impact on the regulatory sector. The European Medicines Agency (EMA) will leave London and relocate to Amsterdam. This will be a serious logistical challenge for the EMA, which is in charge of the centralised European marketing authorisation procedure for medicinal products and the safety of medicines in Europe. After Brexit, the UK will be excluded from ordinary participation in this procedure.

RECOGNITION OF EXISTING MARKETING AUTHORISATIONS

The United Kingdom must now immediately create national rules for the recognition of centralised marketing authorisations of medicinal products. The approval of new medicinal products will have to be based on national procedures conducted by the competent UK authority, the Medicines and Healthcare Products Regulatory Agency (MHRA). This new environment might diminish the attractiveness of the British pharmaceutical market for European pharmaceutical manufacturers.

British companies must also be prepared for consequences in other EU-related areas. Besides the marketing authorisation of medicines, this includes clinical studies, pharmacovigilance, and research funding, as well as the collaborative work of the European Network for Health Technology Assessment (EUnetHTA) in evaluating the effectiveness of medicinal products, for which the European Commission has recently issued a draft regulation.

THE BAH IS CALLING FOR MUTUAL RECOGNITION OF PROCEDURES

In principle, existing centralised European marketing authorisations of medicinal products, as well as those granted in decentralised procedures, ought to remain valid and be recognised by the UK without any restrictions. Only this approach will ensure that the British market remains open to European pharmaceutical manufacturers, so that British patients continue to have access to medicines.

The United Kingdom plays an important role as a Reference Member State, or as a future Concerned Member State, in European marketing authorisation procedures. Presumably several thousand existing marketing authorisations will now have to be transferred to other national competent authorities within the EU27. New rules will have to be established for UK participation in European marketing authorisation procedures for new medicines. Any impairment of the excellent efficiency of the European marketing authorisation system, or of the assurance of the safety of medicines, would not be acceptable under any circumstances.

ACCESS TO MEDICINES MUST BE GUARANTEED

The timetable for the highly complex negotiations is very ambitious, and political tactics still seem to dominate. The BAH has been actively encouraging its member companies to prepare for the worst case scenario, namely that of the UK leaving the EU without any further arrangements. Notwithstanding the tight time frame, it is possible for the negotiation parties to easily establish Mutual Recognition Agreements (MRAs) for the time being, in order to define cooperation and standards. This task should not be overly complex, since most standards are currently identical due to the EU framework. Hopefully, the Brexit negotiations will deliver the right results for patients and companies alike, in order to ensure continuous access to medicines in the EU and The UK.

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The BAH has been engaged on Brexit with the German federal government and British industry associations. It has hosted events on the consequences of Brexit and has published a guideline document on the subject in German and English. At the European level, the BAH is represented by its European umbrella organisation, the AESGP.